

**UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION**

WAVE NEUROSCIENCE, INC. a Delaware Corporation,

Plaintiff,

vs.

BRAIN FREQUENCY LLC, a Texas Limited Liability Company

Defendant.

Case No. 5:23-CV-00626-XR

Honorable: Xavier Rodriguez

**DECLARATION OF MAROM BIKSON IN
SUPPORT OF PLAINTIFF’S OPENING
CLAIM CONSTRUCTION BRIEF**

1. I have been asked by Plaintiff Wave Neuroscience, Inc. to provide this declaration concerning the meaning of certain claim terms in certain patents at issue in the above-captioned consolidated case. Specifically, I have been asked to provide my opinions on how a person of ordinary skill in the art (“POSITA”) would have understood the use of the various claim terms as used in the claims of U.S. Patent Nos. 10,029,111 (“the ’111 Patent”), 8,926,490 (“the ’490 Patent”), 8,870,737 (“the ’737 Patent”), and 8,465,408 (“the ’408 Patent”) (collectively, “Asserted Patents”) that are being asserted against the Defendants in this case.

I. PROFESSIONAL BACKGROUND AND QUALIFICATIONS

2. I am a Professor at the City University of New York in the Department of Biomedical Engineering. I currently teach graduate and undergraduate level biomedical engineering courses, including on biomedical instrumentation. I have previously taught or presented guest lectures at many other universities on neurological stimulation.

3. I earned my undergraduate degree in biomedical engineering from Johns Hopkins University in 1995. I received a Ph.D. in biomedical engineering from Case Western Reserve University in 2000.

4. I have been involved in biomedical research since 1995. I have been teaching

graduate level courses in biomedical engineering since 2003. My research includes numerous past and current projects researching neuromodulation and nerve stimulation. Beginning in 2005, I was involved in grant-funded research on the effect of application of electrical fields on the brain.

5. In addition to teaching and research, I am an elected member of the American Institute for Medical and Biological Engineering. I have also served as an editor for a number of scientific journals and texts including Brain Stimulation. I am also on the Board of Directors for the North American Neuromodulation Society.

6. I have also authored or co-authored nearly 500 articles, texts, and chapters in my field of expertise, including dozens of publications specifically directed to transcranial electrical and magnetic stimulation (tES and TMS).

7. My background and qualifications are more fully set forth in my curriculum vitae, attached as Exhibit 1.

II. STATEMENT OF COMPENSATION

8. I am being compensated for the time I spend on this matter at my usual and customary consulting rate of \$600 per hour. This compensation is not contingent in any way on the outcome of this case or the testimony I provide.

III. MATERIALS CONSIDERED

9. In addition to relying on my knowledge and experience in the field of EEG, tES, TMS and neuromodulation, I also considered or relied upon the list of documents attached as Exhibit 2 in preparing this Declaration and forming my opinions contained herein..

10. In particular, I have reviewed and considered the Asserted Patents, their respective prosecution histories, and the documents cited in this declaration in providing my opinions stated herein.

IV. PERSON OF ORDINARY SKILL IN THE ART

11. It is my understanding that at the claim construction stage of a case, the claims are interpreted from the perspective of a POSITA as of the priority dates of the patents. In this case,

I have been asked to assume that: (1) the priority date of the '111 Patent is April 6, 2012, (2) the priority date of the '490 Patent is September 24, 2008, (3) the priority date of the '737 Patent is September 24, 2008, and (4) the priority date of the '408 Patent is August 6, 2009.

12. I am informed that the POSITA is a hypothetical person who is presumed to have known the relevant art at the time of the invention.

13. It is my opinion that a POSITA at the time of the invention would have been someone having knowledge and familiarity with electrophysiology and signal processing. Sufficient familiarity and experience with the subject matter of the asserted patents could be obtained by: (i) successfully completing a Bachelor's degree in Electrical Engineering or Biomedical Engineering or similar discipline with classes or experience directed to electrophysiology and signal processing and TMS; (ii) a medical degree focusing on treatment of patients with brain disorders and experience with EEG and application of electrical or magnetic energy such as TMS; or (iii) at least three (3) years of experience in a job working with patients having brain disorders using treatment protocols involving TMS and EEG/electrophysiology.

14. The earliest indication that rTMS could be used for depression was in 1993, but the technology was not fully developed in 2008. Later in the same year, the FDA cleared the technology for the limited use of depression. Until that time, there was no on-label use for rTMS, outside of research settings.

15. At the time of the inventions, TMS was still a developing technology. Accordingly, there were limited regulatory approvals in place for the use of TMS in treating mental health disorders, nor was TMS in wide use in medical settings. Therefore, medical experience at that time would have consisted largely of concentrated research efforts into specific clinical conditions using predominant theories of TMS action at the time, which were the activation or inactivation of brain tissue given high or low frequency applications of TMS. While a medical degree focusing on the relevant practice area might have been one possible avenue for gaining ordinary skill in the art at the time of the inventions, it was not the only avenue. A medical degree, without the requisite experience focusing on treatment of patients

with brain disorders and experience with EEG and application of electrical or magnetic energy such as TMS, is neither necessary nor sufficient to acquire the necessary skills to be a POSITA.

16. Additionally, the creation or improvement of TMS technology would have been outside the conventional realm of MDs. To be an active participant at that time, one would have had to have an understanding of the underlying technology and hardware. I do not believe that a medical degree alone would have afforded the requisite knowledge of EEGs, coils, intrinsic frequencies, Q-factors, and other technical concepts set forth in the Asserted Patents.

V. CLAIM CONSTRUCTION PRINCIPLES

17. I understand that a claim term is typically given its plain and ordinary meaning as it would be understood by a POSITA in the context of the patent claims and the patent specification. In order to understand the plain and ordinary meaning of the claim term, a POSITA must look to the patent claims and specification. I understand that it may also be appropriate to look to the record of a patentee's communication with a patent office during prosecution to obtain the patent—the prosecution history—to understand the meaning of claim terms. Together the patent (figures, specification, and claims) and its prosecution history constitute the intrinsic evidence that should be the primary source used by a POSITA in an effort to understand the meaning of any claim term.

VI. TECHNICAL BACKGROUND

18. The '408 Patent provides a method and a device for use in treating a number of mental health disorders, by gently tuning the brain and affects symptoms of the mental health disorders without the use of medication, using a magnetic field to influence an intrinsic frequency within a specified EEG band, a Q-Factor of the intrinsic frequency within a specified EEG band, a coherence value within the specified EEG band, or an EEG phase of the specified EEG frequency of the subject toward a pre-selected or target intrinsic frequency within the specified EEG band, Q-Factor of the intrinsic frequency within a specified EEG band, coherence value within the specified EEG band, or EEG phase of the specified EEG frequency, respectively.

19. The '737 Patent provides a method for a novel, inexpensive, and easy to use therapy for a number of mental health disorders that gently tunes the brain and affects mood, focus, and cognition of a subject, by using a magnetic field to influence an intrinsic frequency within a specified EEG band or a Q-Factor of the intrinsic frequency within a specified EEG band of the subject toward a pre-selected or target intrinsic frequency within the specified EEG band or Q-Factor of the intrinsic frequency within a specified EEG band, respectively.

20. The '490 Patent provides a system for treating mental health disorders that gently tunes the brain, by using a magnetic field to move an intrinsic frequency within a specified EEG band, a Q-Factor of the intrinsic frequency within a specified EEG band, a coherence value within the specified EEG band, or an EEG phase of the specified EEG frequency of the subject toward a pre-selected or target intrinsic frequency within the specified EEG band, Q-Factor of the intrinsic frequency within a specified EEG band, coherence value within the specified EEG band, or EEG phase of the specified EEG frequency, respectively.

21. The '111 Patent provides a method for improving a physiological condition or a neuropsychiatric condition of a human mammal by subjecting the human to repetitive transcranial magnetic stimulation ("rTMS") at the frequency or pulse rate of a non-EEG biological metric or harmonic or sub-harmonic of the metric, which is chosen based on the cognitive element or symptom that is targeted and designed to be closest to a desired EEG frequency.

VII. "[A METHOD OF] IMPROVING A PHYSIOLOGICAL CONDITION OR A NEUROPSYCHIATRIC CONDITION"

22. I understand that the parties disagree about the proper construction of the phrase "[A method of] improving a physiological condition or a neuropsychiatric condition" as that phrase appears in Claim 1 of the '111 Patent. Defendant asserts that the claim is indefinite and unpatentable subject matter and provides no proposed construction for the phrase, while Plaintiff asserts that the phrase means "to make or become better [the medical condition(s) set forth in the claim]. The parties' current proposed constructions are set forth in the chart below.

Claim Term	Plaintiff's Construction	Defendants' Construction
[A method of] improving a physiological condition or a neuropsychiatric condition '111 Patent, claim 1;	to make or become better [the medical conditions in the claim]	Indefinite and unpatentable subject matter.

23. Claim 1 of the '111 Patent states:

A method of improving a physiological condition or a neuropsychiatric condition of a mammal which comprises subjecting the mammal to repetitive transcranial magnetic stimulation (rTMS) at a frequency of a non-EEG biological metric, or an harmonic or sub-harmonic of said non-EEG biological metric, wherein the mammal is a human.

24. Clinical trials in both the United States and worldwide have demonstrated the efficacy of TMS in treatment of neuropsychiatric symptoms in mental health. The use of TMS for the treatment of neuropsychiatric conditions such as depression was first suggested in approximately 1993, and FDA approval was given for this use in 2008. Likewise, the application of magnetic fields (as in tES and TMS) in treating neuropsychiatric conditions was actively being researched at the time the '111 Patent was filed. Consequently, a POSITA understood in 2012 that magnetic fields could be used to improve the condition of subjects suffering from a wide variety of neurological maladies. The question that the '111 Patent addresses was not *whether* it could improve a physiological condition or a neuropsychiatric condition – that aspect was already known – but how best to achieve such desired results.

25. As an initial matter, the term “improving” is commonly used in psychiatric and neurological research when discussing a subject’s response to treatment and its meaning would immediately be understood by a POSITA, without further definition. Physiological conditions and neuropsychiatric conditions are associated with a number of clinical symptoms.

26. I have been informed that the Court in the co-pending, PeakLogic Case¹ construed the word “improves” as appearing in U.S. Patent No. 9,446,259, entitled, “Systems and Methods for Neuro-EEG Synchronization Therapy” (the “’259 Patent”), to mean “to make

¹ Case No. 3:21-cv-01330 (S.D. Cal.).

or become better [the medical conditions in the claims]”. See Ex. C (Tache Dec.) at *2. While the ’111 Patent and the ’259 Patent use different biological metrics to generate the specific TMS treatment plans, both patents are: (i) related to improvements in TMS therapy; (ii) have one of the named co-inventors in common; and (iii) are both owned by Wave.

27. In addition, a google scholar search of “transcranial magnetic stimulation” and “improving” limited to the time period between 1980 and 2012, returns 8,940 results (largely scientific publications). Another google scholar search of “transcranial magnetic stimulation” and “improves” limited to the time period between 1980 and 2012, returns 10,700 results (also largely scientific publications). The fourth such result is “Transcranial magnetic stimulation: applications in neuropsychiatry” and has been cited 740 times. It seems irrational to suggest the term has no meaning in TMS (much less medicine) when it is used commonly in context.

28. The Plaintiff’s construction as shown in the chart above is, therefore, fully in line with my understanding of how that term would be interpreted by a POSITA.

29. I understand that Defendants have not offered a proposed construction for the phrase “[A method of] improving a physiological condition or a neuropsychiatric condition.” Instead, I understand that Defendants have taken the position that the phrase is indefinite and unpatentable subject matter. I have been informed that a patent claim is indefinite if the claim, read in light of the specification, fails to inform a POSITA about the scope of the claim with reasonable certainty.

30. I do not agree that the phrase is indefinite because, as explained above, the phrase has a plain meaning that would have been clear to a POSITA upon reading the phrase as it appears in the asserted claim.

31. Claim 1 of the ’111 Patent describes a “method of improving a physiological condition or a neuropsychiatric condition of a mammal” by subjecting the mammal (human) to rTMS at a frequency of a non-EEG biological metric or a harmonic or sub-harmonic of the same. Dkt. 029-02, ’111 Patent, 7:54-59.

32. In addition to the language of the claims, the specification provides additional

guidance regarding the meaning of “[A method of] improving a physiological condition or a neuropsychiatric condition.”

33. According to the specification:

“Transcranial magnetic stimulation and rTMS have been used to treat many psychological and medical disorders such as major depressive disorder, Parkinson's disease, Alzheimer's disease, autism spectrum disorder (ASD), schizophrenia and others.”

Dkt. 029-02, '111 Patent, 1:24-28.

34. The specification further discloses:

“An improvement in a physiological condition, psychological condition, or a neuropsychiatric condition exhibited by the mammal is achieved.”

Dkt. 029-02, '111 Patent 1:41-44.

35. According to the specification:

By modulating the brain activity of a mammal, *improvements* in physical conditions, psychological conditions, and neuropsychiatric conditions are *improved* in a non-invasive manner and usually without the need for medications. Physical conditions that can be *improved* include pain relief (pain management), blood pressure, stress, libido, motor function, physical performance, height (in children) or weight. Psychological conditions that can be *improved* included concentration/focus, sleep, alertness, memory, speech, intelligence, and other cognitive functions. Neuropsychiatric conditions that can be *improved* include symptoms of Autism Spectrum Disorder (ASD), Alzheimer's disease, attention deficit hyperactivity disorder (ADHD), schizophrenia, anxiety, depression, coma, Parkinson's disease, substance abuse, bipolar disorder, a sleep disorder, an eating disorder, tinnitus, traumatic brain injury, post-traumatic stress disorder (PTSD), or fibromyalgia.

Dkt. 029-02, '111 Patent, 1:59-2:8 (emphasis added).

36. The specification discloses:

Neuropsychiatric conditions that can be improved include symptoms of Autism Spectrum Disorder (ASD), Alzheimer's disease, attention deficit hyperactivity disorder (ADHD), schizophrenia, anxiety, depression, coma, Parkinson's disease, substance abuse, bipolar disorder, a sleep disorder, an eating disorder, tinnitus, traumatic brain injury, post-traumatic stress disorder (PTSD), or fibromyalgia.

Dkt. 029-02, '111 Patent, 2:1-8.

37. The specification also discloses:

“Alpha band is normally found during periods of relaxation while closing the eyes. Physiologically it is associated with the process of inhibition control. Lack of alpha activity is found in autism, and other mental disorders, such as anxiety,

schizophrenia, and ADHD. Reduced alpha frequency coherence has been found in patients with Alzheimer's disease. Excessive alpha activity may be seen in comatose conditions. In general, rTMS in this range will help treat autism, reduce anxiety, increase attention, or treat schizophrenia and Alzheimer's."

Dkt. 029-02, '111 Patent, 4:1-11.

38. The specification also discloses:

"Beta band is associated with alertness, busy or anxious thinking. Significant reduction of beta activity is often found in subjects treated with benzodiazepines. rTMS in this range will help to increase alertness."

Dkt. 029-02, '111 Patent, 4:13-17.

39. The specification further discloses:

"Gamma activity displays during cross-modal sensory processing or short term memory matching of recognized objects, sounds, or tactile sensations. A decrease in gamma band activity may be associated with cognitive decline, such as Alzheimer's disease. rTMS in this range is used to **treat** cognitive deficits in Alzheimer's disease or other forms of dementia."

Dkt. 029-02, '111 Patent, 4:18-26.

40. The specification further relies on clinical assessments, which provide a baseline against which the treatment's effectiveness in reducing the patient's symptoms for the conditions can be measured after treatment.

41. For example, the specification in "Example 1" describes treatment of autism in a 9-year old boy wherein the boy was treated with rTMS to adjust his alpha frequency:

"Single-lead ECG showed a regular heartbeat at 1.5 Hz. Taking its 6th higher harmonic, it was decided to set the rTMS at 9.0 Hz over the mid-central and left frontal lobe. Following the first 2 sessions of rTMS, the patient showed some degree of improvement with more vigilance and spontaneous communication. With further treatments there was a significant reduction of the slow waves in the patient's EEG and an increase in alpha rhythm. Clinically, the frequency of seizure episodes reduced significantly. After titrating down the anticonvulsant dosage over time, the patient experienced a significant improvement in cognitive and motor functions."

Dkt. 029-02, '111 Patent 7:1-12.

42. The specification in "Example 2" describes treatment and pain management in an adult male after suffering for years after multiple back surgeries:

“Single-lead ECG showed a regular heartbeat at 1 Hz. Taking its 9th higher harmonic, it was decided to set the rTMS at 9 Hz over the bilateral pre-frontal lobe. Following 3 sessions of rTMS, the patient showed a significant reduction in pain. The EEG pattern showed significant improvement in alpha synchronization.”

Dkt. 029-02, '111 Patent, 7:21-26.

43. The specification in “Example 3” describes treatment of an 85-year old adult female who had been diagnosed with Alzheimer’s Disease 15 years prior to treatment and who was suffering memory loss:

“The patient's EEG showed alpha peak frequency below 8 Hz which is in the theta band range. Single-lead ECG showed a regular heartbeat at 1.2 Hz. Taking its 7th higher harmonic, it was decided to set the rTMS at 8.4 Hz over the bilateral pre-frontal lobe. Following 1 session of rTMS, the patient showed a significant improvement in short term memory and working memory. After 2 weeks of daily (Monday-Friday) rTMS sessions the patient became more coherent and her MMSE score improved from 14 pre-treatment to 21 post treatment. The EEG pattern showed an alpha wave near 8 Hz.”

Dkt. 029-02, '111 Patent, 7:35-43.

44. Other claims also provide additional guidance regarding the meaning of “[A method of] improving a physiological condition or a neuropsychiatric condition.”

45. For example, Claim 5 of the '111 Patent discloses:

“The method of claim 1 wherein the physiological condition is concentration, sleep, alertness, memory, blood pressure, stress, libido, speech, motor function, physical performance, cognitive function, intelligence, height or weight.”

Dkt. 029-02, '111 Patent at 8:7-11

46. Claim 6 of the '111 Patent discloses:

“The method of claim 1 wherein the neuropsychiatric condition is Autism Spectrum Disorder (ASD), Alzheimer's disease, ADHD, schizophrenia, anxiety, depression, coma, Parkinson's disease, substance abuse, bipolar disorder, a sleep disorder, an eating disorder, tinnitus, traumatic brain injury, post-traumatic stress syndrome, chronic pain or fibromyalgia.”

Dkt. 029-02, '111 Patent at 8:12-17.

47. I have seen the aforementioned passages from the specification and claims of the '111 Patent. Based on these passages from the specification and claims, a POSITA would understand the claim term as Plaintiff has proposed.

48. With respect to the prosecution history for the '111 Patent, Claim 1 was amended in a preliminary amendment to include the claim limitation in the preamble of “improving a physiological condition or a neuropsychiatric condition”. *See* Ex. 3, '111 Prosecution History, at p. *44 (June 18, 2016 Preliminary Amendment p.2).

49. I also see that during prosecution of the '111 Patent, the Examiner had no trouble understanding the phrase “[A method of] improving a physiological condition or a neuropsychiatric condition” in the claims. Upon reading the claim, the Examiner first rejected the claim, citing other terms that were allegedly indefinite. *See* Ex. 3, '111 Prosecution History, at p. *62 (Oct. 21, 2016 Non-Final Office Action, p. 2).

50. It is also my opinion that the phrase “[A method of] improving a physiological condition or a neuropsychiatric condition” is not purely subjective. Rather a determination of whether a symptom has “improved” requires the application of specialized medical or scientific knowledge to a known problem. Thus, although it requires a clinical assessment, it is not subject to the whims of the researcher or physician, but is based on a comparison to known or established scientific baselines.

51. A POSITA would understand that the claims of the '111 Patent use the term “improving” to describe the clinical purpose of making or becoming better the symptoms associated with the physiological and neuropsychiatric conditions, and would know how to evaluate whether symptoms have been made better after treatment.

52. Furthermore, the term “improving” is commonly used in scientific literature and by medical associations and government entities (NIH, FDA, e.g.) to describe medical conditions that were made or became better, just as described in the '111 Patent. Thus, the specification uses “improvement” and synonymous words consistent with a POSITA’s understanding of its plain meaning.

53. According to the Merriam Webster dictionary, improve means, “to enhance in value or quality: **make better**.” “Improve.” *See* Ex. 4, *Merriam-Webster Dictionary*, Merriam-Webster, <https://web.archive.org/web/20060904110832/https://www.merriam->

webster.com/dictionary/improve. Accessed 11 May 2024. Copyrighted 2006. Recorded September 4, 2006. Therefore, the definition provide is in agreement with Plaintiff's construction.

54. According to the Medical Dictionary for the Health Professions and Nursing, improvement means "[t]he act or process of making better." "Improve." *See* Ex. 5, *Medical Dictionary for the Health Professions and Nursing*. <https://medical-dictionary.thefreedictionary.com/improve>. Accessed 11 May 2024. Therefore, improving has a consensus meaning.

55. I also understand that Defendant uses "improving" on its own website. Defendant's website (www.brainfrequency.ai) repeatedly uses the term "improving" consistent with Wave's proposed construction in this case (emphasis added): "The Brain Frequency™ AI system is an innovative therapeutic approach to improving brain health and wellness." Ex. B (Tache Dec.).

56. Defendant's website further states that "TMS treatment has traditionally been used to manage depression. However, TMS therapy does not use qEEG to tailor treatment plans to individual needs. Brain Frequency™ is an individualized approach to TMS and is more effective as each patient's brain has a unique frequency needed for optimal performance. Brain Frequency™ has dramatically improved the treatment of patients with major depressive disorders, post-traumatic stress, TBI, anxiety, addictive disorders, ADHD, sleep disorders, and OCD." Ex. B (Tache Dec.).

57. Such references to "improving" appearing on Defendant's own website today are instructive of the fact that Defendant and researchers, like a POSITA and a lay person, clearly understand the meaning of the term "improving" in the context of the technology disclosed and claimed in the '111 Patent.

58. In summary, it is my opinion that a POSITA would understand the meaning of "[A method of] improving a physiological condition or a neuropsychiatric condition" to be synonymous with make or become better [the medical conditions in the claim], as proposed by

the Plaintiff. Furthermore, a POSITA would understand the meaning of the phrase and the scope of the claims in which it appears with reasonable certainty.

VIII. “INTRINSIC FREQUENCY”

59. I understand that the parties disagree about the proper construction of the term “intrinsic frequency” as that term appears in claim 1 of the ’490 Patent, claims 1-2, 12, and 20 of the ’408 Patent, claims 3 and 7 of the ’111 Patent, and claims 1-2 and 4 of the ’737 Patent. I understand that preselected intrinsic frequency is construed elsewhere.

60. I understand that the Plaintiff asserts that the intrinsic frequency is a frequency selected to which treatment is to be applied. I further understand that the Defendant asserts that the intrinsic frequency is the frequency (f_0) at which peak signal power in the specified band (E_{max}) is located. For the ’111 Patent, I also understand that Defendant proposes the same construction but also asserts, in the alternative, that the term is “indefinite & invalid: not enabled/lacking written description.” The parties’ current proposed constructions are set forth in the chart below.

Claim Term	Plaintiff’s Construction	Defendant’s Construction
Intrinsic frequency ’490 Patent, Claim 1 ’408 Patent, Claims 1-2, 12, 20 ’111 Patent, Claims 3, 7 ’737 Patent, Claims 1-2, 4	frequency selected to which treatment is to be applied	The frequency (f_0) at which peak signal power in the specified band (E_{max}) is located For ’111 Patent: Indefinite & Invalid: Not enabled/lacking written description or In the alternative: “the frequency (f_0) at which peak signal power in the specified band (E_{max}) is located”

61. Each subject has their own internal, i.e. intrinsic, frequency which can be measured by an EEG. The subject’s intrinsic frequency forms an important component in the asserted patents.

62. Plaintiff's construction is consistent with the asserted claims. For example, Claim 2 of the '408 Patent covers "a method of treating . . . comprising moving at least one of: an intrinsic frequency of a brain of the subject within a specified EEG band toward a pre-selected intrinsic frequency within the same specified EEG band." Dkt. 029-03, '408 Patent, 66:54-56.

63. In addition to the language of the claims, the specification provides additional guidance regarding the meaning of intrinsic frequency. For example, the '408 Patent discloses:

"In another aspect are devices comprising a means for applying a magnetic field to a head of a subject; whereby the means for applying the magnetic field is capable of **influencing an intrinsic frequency** of a brain of the subject within a specified EEG band."

Dkt. 29-3, '408 Patent at 7:12-16 (emphasis added).

64. The '408 Patent also discloses:

"In one aspect are methods of modulating the electrical activity of a brain in a subject in need thereof, comprising: (a) adjusting output of a magnetic field *for influencing an intrinsic frequency* of a specified EEG band of the subject toward a target intrinsic frequency of the specified EEG band; and (b) applying said magnetic field close to a head of the subject.

Dkt. 029-03, '408 Patent 1:40-45 (emphasis added).

65. The '408 Patent also discloses:

"FIG. 5 shows a sample EEG segment for a subject before therapy is delivered. The block on the left shows a time series EEG while the subject is sitting at rest with eyes closed. The block in the center shows the energy across the frequency spectrum for the sampled EEG. The vertical line drawn through the peaks is at 9.1 Hz, the subject's intrinsic alpha frequency. The circle at the right shows the distribution of EEG energy at the intrinsic alpha frequency throughout the scalp, looking down on the top of the subject's head. In the circle representation, the majority of the EEG energy at the [intrinsic] alpha frequency is concentrated at the back of the brain."

Dkt. 029-03, '408 Patent, 15:5-15.

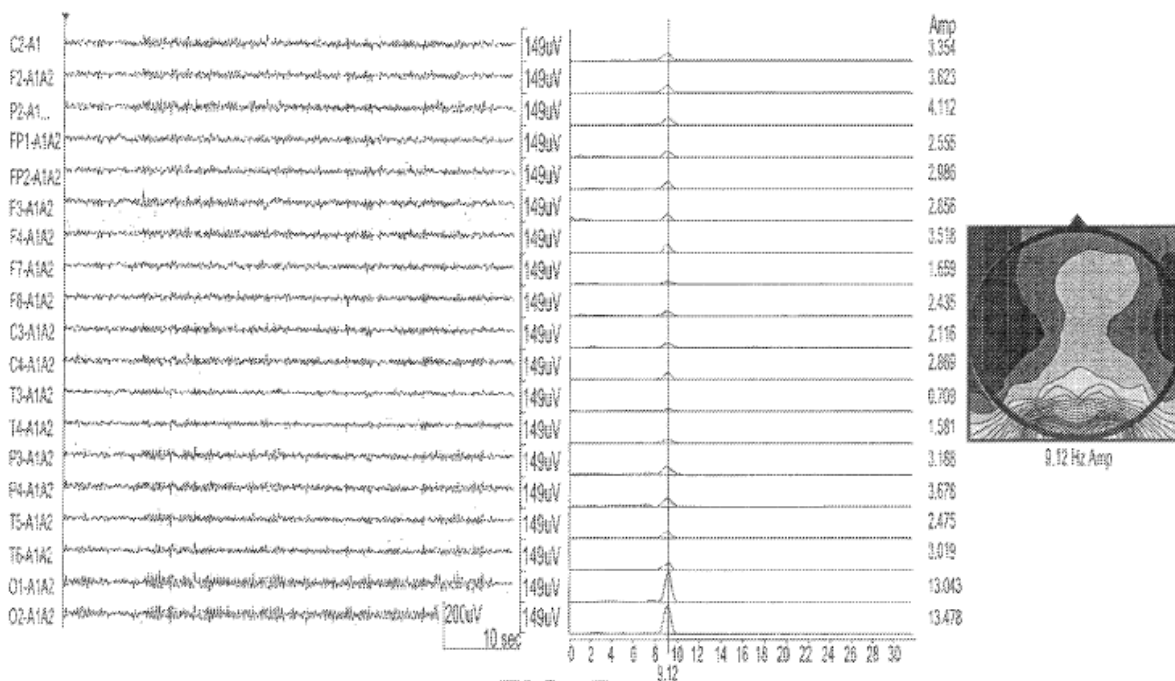


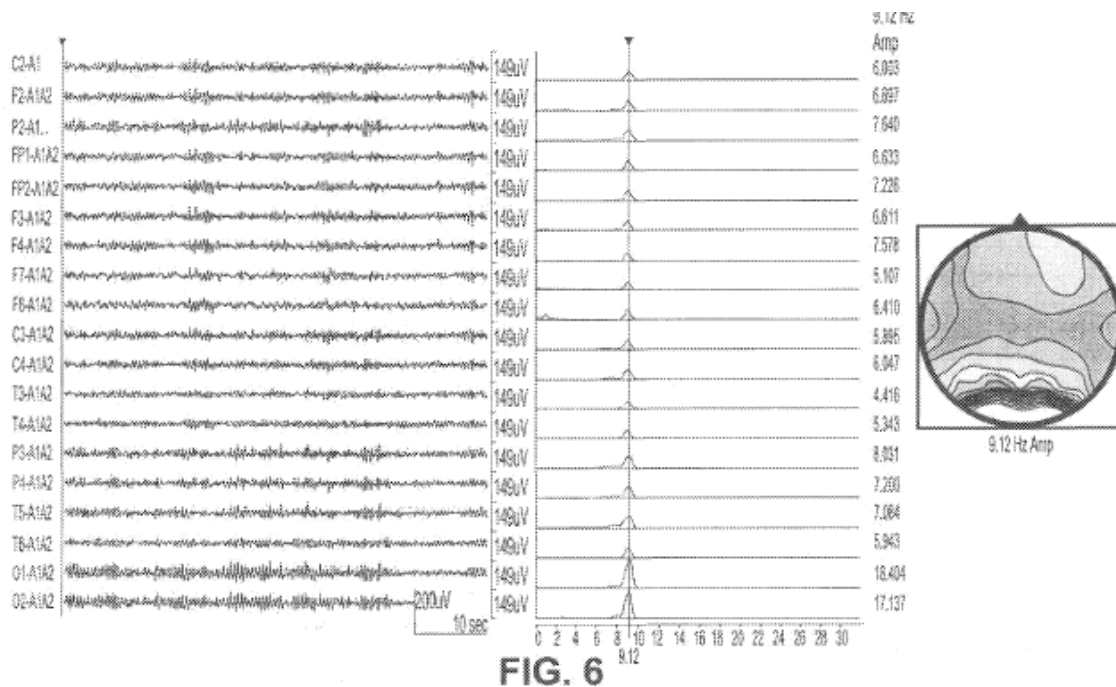
FIG. 5

66. I understand that the inclusion of the word “alpha” within “intrinsic alpha frequency” refers to a subject’s intrinsic frequency within the selected alpha band. Brainwaves are organized into different frequency “ranges” or “bands”, as measured by an EEG, using Greek numerals. The most commonly studied waveforms include delta (0.5 to 4Hz); theta (4 to 7Hz); alpha (8 to 12Hz); sigma (12 to 16Hz) and beta (13 to 30Hz). *See* <https://www.ncbi.nlm.nih.gov/>.

67. The ’408 Patent also discloses:

“FIG. 6 is similar to FIG. 5, except the EEG was sampled immediately following therapy. In this, it can be seen that the energy associated with the intrinsic alpha frequency has increased significantly. From the circle representation on the right, it can be seen that the distribution of energy at the intrinsic alpha frequency throughout the head is more uniform, though the majority of energy is still concentrated at the back of the brain.”

Dkt. 029-03, ’408 Patent, 15:16-23.



68. The '490 Patent discloses:

"In another aspect are methods of using a Transcranial Magnetic Stimulation (TMS) device for influencing an intrinsic frequency of a subject within a specified EEG band, comprising: (a) adjusting output of said TMS device; (b) changing EEG frequency, Q-factor, or coherence by repetitive firing of a magnetic field using said TMS device; and (c) applying said magnetic field close to a head of the subject."

Dkt. 029-04, '490 Patent, 7:4-10. The '737 Patent contains a similar disclosure. *See* Dkt.

029-05, '737 Patent 7:1-7.

69. The '490 Patent also discloses:

"Likewise, a subject who has MDD may have an EEG waveform such as shown in FIG. 35 c, and treating such a subject with a device and or by a method provided herein may still provide the improvement in their depression noted herein by shifting their intrinsic frequency, changing their Q-factor, and/or changing their coherence, etc."

Dkt. 029-04, '490 Patent, 35:49-60. The '737 Patent contains a similar disclosure. *See*

Dkt. 029-05, '737 Patent 34:18-24.

70. The '490 Patent further discloses:

“Provided herein is a method of altering an intrinsic frequency of a brain of a subject within a specified EEG band, comprising determining the intrinsic frequency of the subject within the specified EEG band; comparing the intrinsic frequency from step (a) to an average intrinsic frequency of a healthy population database; if the intrinsic frequency from step (a) is higher than the average intrinsic frequency of the healthy population database, shifting down the intrinsic frequency of the subject by applying a specific magnetic field close to a head of the subject, wherein said specific magnetic field has a frequency lower than the intrinsic frequency of the subject; and if the intrinsic frequency from step (a) is lower than the average intrinsic frequency of the healthy population database, shifting up the intrinsic frequency of the subject by applying a specific magnetic field close to a head of the subject, wherein said specific magnetic field has a frequency higher than the intrinsic frequency of the subject. In some embodiments, a NEST device, such as one of the NEST devices (pMERT devices) described herein is used to create the magnetic field of the method.”

Dkt. 029-04, '490 Patent, 58:16-35. The '737 Patent contains a similar disclosure. *See*

Dkt. 029-05, '737 Patent 53:6-26.

71. The '490 Patent further discloses:

“Provided herein is a method comprising adjusting an output of an electric alternating current source for influencing an intrinsic frequency of an EEG band of a subject toward a target frequency of the EEG band; and applying said electric alternating current across a head of the subject. In some embodiments of the methods, a CES therapy is used to influence the intrinsic frequency of a patient's brain toward a target frequency as measured by EEG.”

Dkt. 029-04, '490 Patent, 64:42-49. The '737 Patent contains a similar disclosure. *See*

Dkt. 029-05, '737 Patent 59:36-43.

72. The '490 Patent further discloses:

“In one aspect are methods of treating a subject, comprising: (a) adjusting output of a magnetic field for ***influencing an intrinsic frequency*** of a specified EEG band of the subject toward a pre-selected or target intrinsic frequency of the specified EEG band; and (b) applying said magnetic field close to a head of the subject.” In other words, treatment is applied to the intrinsic frequency.

Dkt. 029-04, '490 Patent 1:41-46 (emphasis added).

73. The '737 Patent discloses:

“Provided herein is a method comprising: adjusting output of a magnetic field for influencing an intrinsic frequency of a specified EEG band of a subject toward a pre-selected intrinsic frequency of the specified EEG band; and applying said magnetic field close to a head of the subject; wherein the pre-selected intrinsic frequency is a frequency that decreases blood flow in a lower region of the brain of the subject.”

Dkt. 029-05, '737 Patent 31:49-55.

74. The '737 Patent also discloses:

“In one aspect are methods of treating a subject, comprising: (a) adjusting output of a magnetic field for ***influencing an intrinsic frequency*** of a specified EEG band of the subject toward a pre-selected or target intrinsic frequency of the specified EEG band; and (b) applying said magnetic field close to a head of the subject.

Dkt. 029-05, '737 Patent 1:39-44 (emphasis added).

75. The '111 Patent discloses:

“rTMS treatments are then continued *at the intrinsic frequency*. The following Table 1 shows examples of the present invention where rTMS is used to *modify alpha brain waves (intrinsic frequency 8-13 Hz)*.”

Dkt. 029-02, '111 Patent 4:59-63 (emphasis added).

76. The '111 Patent also discloses:

“Various bodily functions operate at frequencies that are harmonics or sub-harmonics of the brain's intrinsic frequency.”

Dkt. 029-02, '111 Patent, 2:39-41 (emphasis added).

77. I have seen the aforementioned passages from the specification of the patents-in-suit. Based on these passages, a POSITA would understand the claim term as Plaintiff has proposed.

78. With respect to the prosecution history for the asserted patents, the '408

Prosecution History discloses:

“Further, Claim 2 of the present invention recites adjusting output of a magnetic field and influencing the subject's intrinsic frequency in a specified EEG band toward a pre-selected intrinsic frequency of *the same* EEG band. On the other hand, Katz's only intention and goal is to move a subject *from a current brain*

state into a desired brain state. Since the brain states correlate to separate EEG bands in Katz (i.e. from relaxed in the alpha band to sleep in the delta or theta band), Katz' methods and devices move the brain waves from one band to another."

Dkt. 029-07, '408 Prosecution History at *800 (September 10, 2012 Amendment in Response to Final Office Action, p. 8) (*italics in original*).

79. The '737 Prosecution History discloses:

"In regards to claims 1 and 2, the prior art of record does not teach or suggest a method as claimed by Applicant, that includes the step of moving at least one of an intrinsic frequency of a specified EEG band of the subject toward a pre-selected intrinsic frequency of the specified EEG band and a O-factor of an intrinsic frequency within a specified EEG band of the subject toward a pre-selected O-factor using said magnetic field."

Dkt. 029-09, '737 Prosecution History at *1508 (March 25, 2014, Final Office Action, p. 5).

80. In the prosecution history for the '490 Patent, in responding to the first office action issued on 9/23/13, dependent claim 18 was amended to describe that the intrinsic frequency can be any frequency between 0.5Hz and about 100Hz in increments of about 0.1Hz. Other than this amendment, the intrinsic frequency was not addressed in the file history for the '490 Patent. Dkt. 029-08, '490 Prosecution History at *1526 (Mar. 19, 2014 Office Action Response, p. 4).

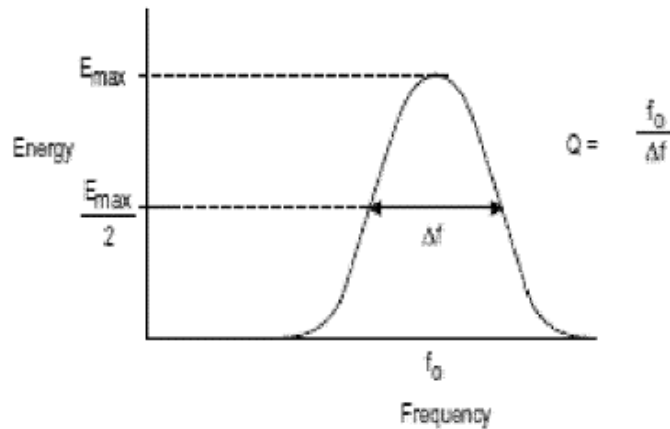
81. In contrast, in my opinion, Defendant's construction is inconsistent with the specifications of the '490 Patent, the '408 Patent, the '111 Patent, and the '737 Patent. I understand that Defendants seek to construe "intrinsic frequency" as "the frequency (f_0) at which peak signal power in the specified band (E_{max}) is located".

82. Defendant's construction appears to be based on an isolated example from the '490 Patent, the '408 Patent, and the '737 Patent which is directed to the Q-Factor, not the intrinsic frequency. For example, column 15, lines 49-59 of the '408 Patent discloses:

FIG. 12 shows an example of the Q-factor as used in this invention. The figure shows a sample graph of the frequency distribution of the energy of an EEG signal. It can be seen that a frequency range, Δf can be defined as the frequency bandwidth for which the energy is above one-half the peak energy. The frequency f_0 is defined as the intrinsic frequency in the specified band. The Q-factor is

defined as the ratio of $f_0/\Delta f$. As can be seen, when ΔF decreases for a given f_0 , the Q-factor will increase. This can occur when the peak energy E_{\max} of the signal increases or when the bandwidth of the EEG signal decreases.

83. Figure 12 of the '408 Patent is disclosed as follows:



84. As shown in the excerpt above, the term “ f_0 ” is defined within this calculation for Q-Factor as the “intrinsic frequency in the specified band”. Defendant then appears to parse the remaining explanation for certain terms used in its proposed construction.

85. Even under Defendant’s selection of a modified and isolated example, Defendant’s Construction does not hold up.

86. The disclosure recited above states in part: “The frequency f_0 is defined as the intrinsic frequency in the specified band.” This sentence does not provide any limits on the meaning of the intrinsic frequency. Rather, this sentence merely points out that the intrinsic frequency will be referred to using the symbol f_0 for purposes of this example.

87. FIG. 12 of the '737 Patent does not otherwise show that the intrinsic frequency is limited to the “the frequency (f_0) at which **peak signal power** in the specified band (E_{\max}) is located” (emphasis added) because f_0 does not point toward any specific portion of the curve represented in FIG. 12. There is no marking that indicates that f_0 is limited to where the E_{\max} is located.

88. In summary, it is my opinion that a POSITA would understand the meaning of

intrinsic frequency” as proposed by the Plaintiff. Furthermore, a POSITA would understand the meaning of the phrase and the scope of the claims in which it appears with reasonable certainty.

IX. “IN-PHASE/IN PHASE”

89. I understand that the parties disagree about the proper construction of the term “in-phase/in phase” as that term appears in claims 1 and 12 of the ’408 Patent and claim 1 of the ’490 Patent.

90. I understand that Plaintiff asserts that the term means waveforms whose peaks and troughs occur at substantially the same time. I further understand that Defendant asserts that the term means waveforms whose peaks and troughs occur at the same time. The parties’ current proposed constructions are set forth in the chart below.

Claim Term	Plaintiff’s Construction	Defendant’s Construction
In-phase/in phase ’408 Patent, Claims 1, 12 ’490 Patent, Claim 1	waveforms whose peaks and troughs occur at substantially the same time.	waveforms whose peaks and troughs occur at the same time

91. The dispute involves whether the peaks and troughs occur at “substantially the same time” or “at the same time”. A POSITA would understand the term as Plaintiff has proposed.

92. In my opinion, Defendant’s construction leads to results in which waveforms that have substantially the same phase are not considered to be in phase.

93. Consider a typical sine wave having the formula of the general form $y(t) = A \sin(2\pi ft + \phi)$ in which A is the amplitude, t is the independent variable, f is the frequency, and ϕ is the phase. A small difference in phase between two waveforms leads to results in which the waveforms are not in-phase.

94. Waveform C may have an amplitude of 1, a frequency of 1, and a phase of $(\pi/2)$. Waveform D may have an amplitude of 1, a frequency of 1, and a phase of $[(\pi/2) + 0.001]$. The difference in phase between Waveform C and Waveform D is about 0.03%.

95. At a value of $t = 0$, Waveform C has a value of 1. At a value of $t = 0$, Waveform

D has a value of 0.9999995. Therefore, the difference in the values of the Waveforms $t = 0$ is less than 0.00005%. Therefore, the difference in percentage between the values of the Waveform C and Waveform D is even less than the difference in percentage between the phases of Waveform C and Waveform D at $t = 0$.

96. This result – that difference in percentage in the value of Waveform C and Waveform D is less than the difference in percentage in the value of the phase at $t = 0$ – is not surprising because the limit of the difference (δ) between Waveform C and Waveform D, as the difference (δ) between the phase goes to 0, is also 0. That is: $\lim_{\tau}(\delta \rightarrow 0)[(\sin(2\pi t + (\pi/2))) - (\sin(2\pi t + (\pi/2 + \delta)))] = 0$. If Defendant is concerned that a small difference in phase may lead to a large difference in results, then their concerns are misplaced. A POSITA would understand that under these circumstances, small differences in phase do not lead to large differences in results. Therefore, a POSITA would understand the term as Plaintiff has proposed.

97. In practice, small phase differences can accumulate over many cycles, such that the waveforms that are in-phase can gradually drift more and more apart so that they can ultimately appear out of phase when in fact they remain in-phase.

98. The specification further establishes that a POSITA would understand the term as Plaintiff has proposed. The '408 Patent recites:

The tensioner assemblies in the embodiments shown in FIG. 17, FIG. 18, and FIG. 19, for non-limiting example, are configured to keep the drive belts taut during use and, therefore, ensure that the rotation of the magnets is simultaneous and generally in-phase as applied to the subject where the magnets are aligned such that each of the neutral planes of each of the three magnets are generally aligned to be parallel to the scalp of the subject.

Dkt. 029-03, '408 Patent, 55:42-49. The '490 Patent contains a similar disclosure. *See*

Dkt. 029-04, 490 Patent, 73:4-11.

99. A POSITA would understand “generally in-phase” as providing flexibility in timing to the term “in-phase.” Therefore, a POSITA would understand the term as Plaintiff has proposed.

X. “OUT OF PHASE”

100. I understand that the parties disagree about the proper construction of the term “Out of phase” as that term appears in claims 1 and 12 of the ’408 Patent and claim 1 of the ’490 Patent.

101. I understand that Plaintiff asserts that the term means “waveforms whose peaks or troughs do not occur at substantially the same time.” I further understand that Defendant asserts that the term means “waveforms whose peaks or troughs do not occur at the same time.” The parties’ current proposed constructions are set forth in the chart below.

Claim Term	Plaintiff’s Construction	Defendant’s Construction
Out of phase ’408 Patent, Claims 1, 12 ’490 Patent, Claim 1	waveforms whose peaks or troughs do not occur at substantially the same time	waveforms whose peaks or troughs do not occur at the same time

102. The dispute involves whether the same time should be modified by “substantially.” For the reasons provided with respect to the term “in-phase/in phase,” a POSITA would understand the term as Plaintiff has proposed.

XI. CONCLUSION

103. The opinions in this declaration are based upon the information I have received so far. I understand that Defendants will be submitting a claim construction brief concurrently with Plaintiff’s brief, and that the Defendants’ brief may be accompanied by a supporting expert declaration. I expect that I will be asked to review Defendants’ submissions and to provide rebuttal or supplemental opinions in response to Defendant’s brief and declaration(s), as necessary. I also am ready and willing to offer testimony at hearing, deposition, or trial if asked to do so.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on May 17, 2024.

A handwritten signature in dark ink, appearing to read "Marom Bikson", is written above a horizontal line.

Marom Bikson, Ph.D.